Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effects of ketamine and pethidine on pain control after surgery in upper and lower limbs orthopedic surgery candidates

Protocol summary

Study aim
Comparison of the effect of ketamine and pethidine on pain control after orthopedic surgery

Design
The randomized double-blind controled clinical trial, phase 3 on 80 patients. ralloc package in stata was used for randomization

Settings and conduct
After selecting the participants from Imam Khomeini Hospital, the patients will be divided into two groups with a random block approach. In the end, the pain score will be measured by considering blinding.

Participants/Inclusion and exclusion criteria
Inclusion: candidate for elective orthopedic surgery with general anesthesia and class I and II in the ASA classification 18 to 60 yrs old No history of opioid addiction Absence of underlying diseases such as liver and kidney failure, history of seizures, pregnancy, and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease, and history of disease respiratory No history of drug sensitivity to pethidine or ketamine Exclusion: opioid addiction underlying diseases such as liver and kidney failure, history of seizures, pregnancy and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease, and history of disease respiratory mental retardation or psychological illness drug sensitivity to pethidine or ketamine chronic use of painkillers

Intervention groups
In the intervention group, Patients will receive ketamine at a dose of 0.3mg/kg 30 minutes after induction of anesthesia. for the control group, Patients will not receive any other drug during anesthesia. After the surgery, when the extubating conditions are suitable, the patient's tracheal tube will be removed and after regaining consciousness, they will receive this medicine at the same dose of 1mg/kg slowly and intravenously.

Main outcome variables
Pain score in two group

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230228057570N1**
Registration date: **2023-07-12, 1402/04/21**
Registration timing: **prospective**

Last update: **2023-07-12, 1402/04/21**
Update count: **0**

Registration date
2023-07-12, 1402/04/21

Registrant information

Name
Hamed Azadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 84 3323 4725

Email address
azadi_eyvan_2012@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effects of ketamine and pethidine on pain control after surgery in upper and lower limbs orthopedic surgery candidates

Public title
Comparison of the effect of ketamine and pethidine on pain control

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
candidate for elective orthopedic surgery with general anesthesia and class I and II in the ASA classification Age range from 18 to 60 years No history of opioid addiction Absence of underlying diseases such as: liver and kidney failure, history of seizures, pregnancy and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease and history of disease respiratory No history of disorders such as mental retardation or psychological illness No history of drug sensitivity to pethidine or ketamine No history of chronic use of painkillers

Exclusion criteria:
opioid addiction underlying diseases such as: liver and kidney failure, history of seizures, pregnancy and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease and history of disease respiratory mental retardation or psychological illness drug sensitivity to pethidine or ketamine chronic use of painkillers

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Balance block randomization method will be used for random allocation of participants. for that, 6 blocks with 4 permutations will be created in the following order 1=KKPP 2=KPKP 3=KPPK 4=PKPK 5=PPKK 6=PKKP where P represents pethidine group and K represents ketamine group. Then, based on the numbers in the random table, a number will be chosen randomly, and based on the last digit on the right, one of the groups will be used to determine the sequence of randomization. It should be noted that if the number on the right side is zero or 7 to 9 when choosing a random number, that number will not be considered and a random number will be selected again. This process, will continue until all 80 participants are assigned to two groups. It should be noted that this method will prevent the unbalance of the two groups as well as the identification of the randomization sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
For blinding, each drug will be assigned a code that can only be identified by the principal investigator and neither the patient nor the person who is collecting data will unknow what drug the patient has taken. For this purpose, the same cover and appearance of the medicine vials will be prepared.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ilam University of Medical Sciences

Street address
Ilam University of Medical Sciences campus, Banganjab, Pazhohesh Blvd

City
Ilam

Province
Ilam

Postal code
6939177143

Approval date
2023-06-18, 1402/03/28

Ethics committee reference number
IR.MEDILAM.REC.1402.060

Health conditions studied

1

Description of health condition studied
Fracture of upper limb

ICD-10 code
T10

ICD-10 code description
Fracture of upper limb, level unspecified

2

Description of health condition studied
Fracture of lower limb

ICD-10 code
S82

ICD-10 code description
Fracture of lower leg, including ankle

Primary outcomes

1

Description
Pain score based on Visual Analogue Scale tool
Timepoint
at recovery room, 6 and 12 hours after surgery
Method of measurement
Visual Analogue Scale tools

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patients in the ketamine group will receive ketamine at a dose of 0.3mg/kg 30 minutes after the induction of anesthesia. For this purpose, the patients will undergo standard monitoring (pulse oximetry, heart rate, blood pressure, and echocardiography) before surgery, and the vital signs of the patients will be evaluated and recorded every 5 minutes in the first 15 minutes. Then this process repeated every 15 minutes. Induction of anesthesia in all patients is as follows: they will be anesthetized with 2mg/kg propofol, 2ug/kg fentanyl, and 0.5mg/kg atracurium, and then the patients will undergo tracheal intubation. Anesthesia will be continued with a mixture of oxygen and nitrous oxide in equal proportions and isoflurane equivalent to MAC and continuous injection of atracurium at a dose of 0.2mg/kg.
Category
Treatment - Drugs

2

Description
Control group: for patients in the pethidine group, the extubation will be done after surgery and in a suitable situation. When patients get consciousness, pethidine will be injected with the dose of 1mg/kg slowly and intravenously, then the patients will be transferred to recovery and under standard monitoring again.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Hamed Azadi
Position
Instructor
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Master
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available